



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,186	07/19/2001	Hideji Tajima	10287.46	9114
27683	7590	03/14/2006	EXAMINER	
HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			CROSS, LATOYA I	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 03/14/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/909,186	<b>Applicant(s)</b> TAJIMA, HIDEJI	
	<b>Examiner</b> LaToya C. Younger	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-44 is/are pending in the application.  
     4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-33 and 36-42 is/are rejected.
- 7) ☒ Claim(s) 34,35,43 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to Applicants' After-Final amendments filed on October 24, 2005. Claims 11-44 are pending. Claims 11-14 are withdrawn from consideration as being directed to non-elected subject matter.

#### *Withdrawal of Rejections from Previous Office Action*

- The anticipation rejection over Vann et al is withdrawn in view of Applicants' argument that Vann et al fail to teach a rolled and unrolled configuration for the base member.

#### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 15-33, 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,057,100 to Heynecker in view of US Patent 6,482,593 to Walt et al.

Heynecker discloses oligonucleotide arrays. The oligonucleotide arrays are fibers, which comprise a support having oligonucleotides attached thereto. Oligonucleotides are substances for detection of analytes in a sample. The fiber support is a base member to which the oligonucleotides are attached and is disclosed as being made from materials such as polyethylene (col. 3, lines 16-35). At col. 4, lines 14-15, Heynecker teaches that the fiber is "flexible". The arrays have at least two different oligonucleotides attached, preferably more than two (col. 4, lines 17-22). Heynecker further discloses that each oligonucleotide species is arranged in distinct linear rows (side by side) to form an immobilized oligonucleotide strip, i.e. an unrolled configuration (col. 4, lines 47-56). With respect to the rolled configuration, Heynecker discloses fibers being spiraled around a center core, as shown in figure

Art Unit: 1743

3D. Further, Heynecker discloses "spacer fibers" to aid in alignment. With respect to the tubular member, Heynecker discloses a casing (105), which houses the fibers that are coiled around the core member. Heynecker discloses that the disks may be rotated through a solution of test sample (col. 6, lines 28-37). The reference also discloses using fluorescent labels to detect the target sequences, wherein a laser source can be used for detection. It would have been obvious to one of ordinary skill in the art to provide the test solution in a container (tubular member) and that the tubular member would have a means to put solution into the container and take solution out of the container. Such would have been obvious because the user would have needed to place the test solution into the container and when the test solution needs to be changed or discarded, the test solution would need to be removed from the container.

Heynecker differs from the instantly claimed invention in that there is no disclosure of oligonucleotides are in a fixed location on the fiber, wherein the location corresponds with a particular chemical structure.

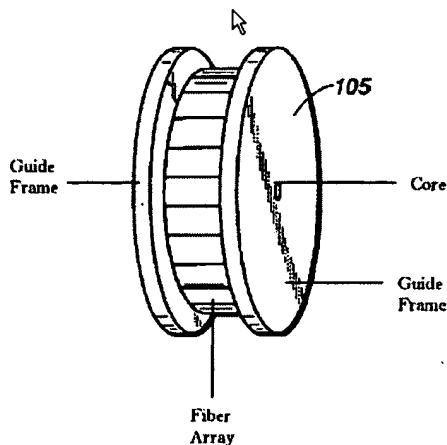
Walt et al teach biosensors for detecting oligonucleotide species in a fluid sample. The biosensors of Walt et al comprise an optical fiber (12) having oligonucleotides attached to the fiber strand (col. 13, lines 24-31). At col. 14, lines 62-64 and col. 15, lines 28-41, Walt et al teach that each oligonucleotide deposit on the fiber serves as one fixed probe immobilized at a predetermined spatial position. Further, Walt et al teach an identifying label, such as a dye, on the fiber to reflect the presence of a target species (col. 18, line 60 – col. 19, line 11).

It would have been obvious to one of ordinary skill in the art to have the oligonucleotides of Heynecker to be attached to the fiber at predetermined locations to allow detection at a particular location to determine the presence of a particular analyte in the sample. Where the oligonucleotides are positioned

Art Unit: 1743

at specific locations on the fiber, the user need only observe the presence of a reaction at that location to determine the presence of a particular analyte in the sample.

Also, Heynecker does not explicitly teach that the casing (105) is made of permeable material. However, such would have been obvious to one of ordinary skill in the art because the casing will be rotated through a sample solution. Thus, if the casing were made of permeable material, then it can be assured that the sample solution reaches the reaction sites on the fibers, providing for accurate detection. Below is a description of figure 3E of Heynecker.



### *Allowable Subject Matter*

3. Claims 34-35 and 43-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Response to Arguments*

4. Applicant's arguments filed October 24, 2005 have been fully considered but they are not persuasive. In response to the obviousness rejection over Heynecker in view of Walt, Applicants argue

Art Unit: 1743

that there is no motivation or suggestion of a base member having a rolled configuration and an unrolled configuration, as recited in claim 15. In response, the Examiner notes that Heynecker does disclose an unrolled configuration as claimed since the reference discloses chemical species arranged in distinct linear rows to form an immobilized oligonucleotide strip. The strip itself is in an unrolled configuration. Applicants argue that a predetermined order of detection substances is not disclosed. However, such would have been obvious in view of the teachings of Walt where spatial position of chemical species is taught. With respect to the rolled configuration claimed, Heynecker does disclose a rolled configuration as claimed since the reference discloses fibers being spiraled around a center core, as shown in figure 3D. With respect to the manner in which the base member is rolled around the cylindrical structure, Applicants argue that the reference fails to teach "circumferentially-extending rolls". First, it should be noted that Applicants' specification fails to specifically point out what is intended by this phrase. Further, it is the position of the Examiner that the base member being wound around the core (figure 3D of Heynecker) is sufficient to meet Applicants' claims. The chemical species on the base members of Heynecker are positioned outwardly (as evidenced by the rolls being able to be rotated through a test solution). It would have been obvious to one of ordinary skill in the art to wound the base members around the core in a manner such that each of the chemical species is exposed to assure contact between the test solution and the chemical species. Depending on the length of the base member, one of ordinary skill in the art would have recognized that the base member may need to be spiraled around the core to assure that all the chemical species are exposed and can make contact with the test solution.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1743

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya C. Younger whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Thursday 10:30 a.m. - 7:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lcy